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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,393	04/02/2004	Cameron Kerrigan	50623.00381	2921

7590 10/31/2007

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EXAMINER	
SELLMAN, CACHET I	

ART UNIT	PAPER NUMBER
1792	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,393	KERRIGAN, CAMERON	
	Examiner	Art Unit	
	Cachet I. Sellman	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 August 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2 and 4-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,and 4-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/16/2007 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1-2, 4-7, and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. (US 6214115) in view of Pacetti (US 6743462).

Taylor et al. discloses a process for coating a stent which comprises inserting the stent over a mandrel having a hollow tubular body and pored disposed on a surface of the mandrel, the pores extending through the tubular body (col. 1, lines 27-28; 42-45). A coating solution is applied to the stent and a vacuum pressure is also applied to the hollow tubular body for extracting some of the coating solution that is applied to the stent (col. 2, line 63 – col. 3, line 1).

Taylor et al. fails to teach applying the vacuum pressure during coating as well as rotating the stent while applying the vacuum pressure as required by **claims 1, 11 and 14**. However, it was well known in the art at the time to rotate while applying the pressure differential and coating the stent as taughy by Pacetti. Pacetti teaches a process for coating a stent where the stent is rotated while a spray coating is being applied. The pressure is adjusted during coating (abstract and fig. 1), by reducing the pressure during coating to below ambient pressure allows for the solvent to evaporate more rapidly which applies the composition to be applied continuously therefore minimizing coating defects such as "pool webs" (see col. 3,line 45 – col. 4, line 10). Pacetti teaches that is was well known in the art to apply coatings to a stent using either spraying or immersion techniques therefore the two are interchangeable.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the process of Taylor et al. to include the steps of applying the vacuum pressure as well as rotating the stent while coating as taught by Pacetti. One would have been motivated to do so because both are directed towards coating stents while minimizing coating defects. Where Taylor et al. teaches applying

the vacuum pressure after coating and Pacetti teaches that when the reduced pressure is applied during the coating the coating can be applied continuously instead of in short bursts when evaporating the coating after it is applied therefore minimizing coating defects.

The composition as taught by Pacetti can be sprayed onto the stent because spraying and immersion are two interchangeable methods of applying the coating to a stent as required by **claim 2**.

As shown by Pacetti, the stent can be coated with a polymer dissolved in a solvent and optionally a therapeutic substance (col. 1, lines 32-40) as required by **claim 4**.

Taylor et al. teaches that the stent is mounted on a mandrel and is affixed by two collars (col. 1,l ines 49-53). The mandrel includes a support member to contact a first end of the stent, another color i.e. a lock member, to contact a second end of the stent and the outer surface of the mandrel contacts the inner surface of the stent as required by claims **5, 7, 12, and 15**.

Taylor et al. further teaches an alternative support design for coating a stent where a plastic sheath having spiral slots formed around its outer surface, which is placed around the external periphery of the mandrel (col. 3, lines 17-23). Therefore the inner surface of the stent does not make contact with an outer surface of the mandrel as required by **clams 6, 13, and 16**.

5. Claims 6-10, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Taylor et al. in view of Pacetti ('462) as applied to claims 1, 11 and 14 above and in further view of Pacetti et al. (US 6565659).

The teachings of Taylor et al. in view of Pacetti ('462) are as stated above. They fail to teach that the mandrel is not in contact with the stent as required by **claims 6, 8-10, and 13**.

Pacetti et al. ('659) discloses an apparatus and process for coating a stent with a polymer and drug composition. The stent is mounted on a mandrel where it does not come in contact with the mandrel in order to minimize or eliminate the amount coating located where the stent and mandrel are in contact with one another (col. 2, lines 56-65). The support comprises of a mandrel that has a diamer smaller than the inner diameter of the stent to prevent the surfaces from contacting one another to avoid the mandrel from obstructing the patter of the stent body during coating (col. 3, lines 56-62). Lock members having coning end portions are provided at the ends, the mandrel can have a bore (see col. 3, line 30 – col. 4, line 29).

It would have been obvious to one having ordinary skill in the art to use the mounting assembly of Pacetti et al. ('659) in the process of Taylor et al. in view of Pacetti ('462) in order to prevent or minimize coating defects associated with the mandrel and stent coming in direct contact with each other especially since both are directed towards coating stents at the same time minimizing coating defects.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cachet I. Sellman whose telephone number is 571-272-0691. The examiner can normally be reached on Monday through Friday, 7:00 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Timothy Meeks can be reached on 571-272-1423. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cachet I Sellman
Examiner
Art Unit 1792

cis

/William Phillip Fletcher III/
Primary Examiner